REMARKS

Claim Amendments

Applicants have hereby cancelled claims 2, 29-32, and 36 and amended claims 4, 6, 9, 13, 15, and 33 to correct certain informalities.

Response to the Obviousness Rejection under 35 U.S.C. §103

In the January 29, 2007 Office Action, the Examiner rejected claims 2, 4, 6, 8-13, 15-26, 28-33, 35, and 36 as allegedly obvious over U.S. Patent No. 5,932,234 to Simon et al. (hereinafter "Simon"), U.S. Patent No. 5,885,565 to Elias et al. (hereinafter "Elias"), and U.S. Patent No. 6,150,381 to Subbiah (hereinafter "Subbiah").

As mentioned hereinabove, claims 2, 29-32, and 36 have already been cancelled. Applicants respectfully traverse the Examiner's rejections of remaining claims 4, 6, 8-13, 15-26, 28, 33, and 35, for the following reasons:

It has been well established that the Examiner bears the **initial burden of presenting a *prima facie* case of unpatentability**. See *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984). If the Examiner at the initial stage does not present a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. Only when the Examiner has met this initial burden, the burden of coming forward with rebuttal evidence or argument shifts to the applicant. See *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992).

Further, it has been well established that when prior art discloses many possible choices without giving any direction or guidance as to which of these many possible choices is likely to be successful, the prior art constitutes at most a suggestion that it would be "**obvious to try**" each of numerous possible choices until one possibly arrived at a successful result, **which is insufficient for supporting *a prima facie* case of obviousness** under 35 U.S.C. §103. See In re Geiger, 815 F.2d 686 (Fed. Cir. 1987); see also Novo Industri A/S v. Travenol Laboratories, Inc., 677 F.2d 1202 (7th Cir. 1982).

The claimed inventions of the present application are directed to topical compositions that **combine at least one protease inhibitor with at least one cell differentiation enhancer** to enhance the skin's natural lipid barrier. Specifically, claim 6, from which claims 4, 8-9, 16-18, 20-21, 23-24, and 26 depend, positively recites a composition comprising: (1) **at least one protease inhibitor**,

which can be, *inter alia*, betulinic acid, boswellic acid, asiatic acid, and cholesterol sulfate, (2) **at least one cell differentiation enhancer**, which is sclareolide. Claim 10, form which claims 11-13, 19, 22, 25, 33, and 35 depend, positively recites a composition comprising: (1) **at least one protease inhibitor**, which is cholesterol sulfate, and (2) **at least one cell differentiation enhancer**, which can be, *inter alia*, sclareolide and Vitamin D_3 analogs. Claim 15, from which claim 28 depends, positively recites a composition for topical application to the skin comprising: (1) **at least one protease inhibitor**, which can be, *inter alia*, betulinol, betulinic acid, asiatic acid, and cholesterol sulfate, (2) **at least one cell differentiation enhancer**, which can be, *inter alia*, sclareolide and vitamin D3 analogs, and (3) **a self tanning agent**, which is DHA.

The Examiner cited multiple prior art references, including Simon, Bissett, Elias, and Subbiah, which disclose uses of numerous cosmetic components and ingredients. However, these prior art references fail to teach or suggest any specific combination of protease inhibitor(s) with cell differentiation enhancer(s), as positively recited by the pending claims of the present application, and more importantly, they do not provide any direction or guidance as to which specific combinations from the laundry lists of cosmetic components and ingredients disclosed therein are likely to be successful in enhancing the skin's natural lipid barrier.

For example, Simon discloses in general a cosmetic and/or dermatological composition comprising: (i) at least 20% by weight of a fatty phase, (ii) at least one fatty ester of a C_5-C_7 carbohydrate, (iii) at least one polyol, and (iv) at least one cosmetic and/or dermatological active agent (see Simon, column 1, lines 63-67 and column 2, lines 1-2). At column 5, lines 66-67 and column 6, lines 1-38, Simon provides a laundry list of about sixty (60) compounds or families of compounds that can be used as the cosmetic/dermatological active agent, including:

1. ascorbic acid and esters thereof,
2. allantoin, citric acid,
3. caffeic acid,
4. salicylic acid and its derivatives,
5. lactic acid,
6. methyllactic acid,
7. glucuronic acid,
8. glycolic acid,
9. pyruvic acid,
10. 2-hydroxybutanoic acid,
11. 2-hydroxypentanoic acid,
12. 2-hydroxyhexanoic acid,
13. 2-hydroxyheptanoic acid,
14. 2-hydroxyoctanoic acid,
15. 2-hydroxynonanoic acid,
16. 2-hydroxydecanoic acid,
17. 2-hydroxyundecanoic acid,
18. 2-hydroxydodecanoic acid,
19. 2-hydroxytetradecanoic acid,
20. 2-hydroxyhexadecanoic acid,
21. 2-hydroxyoctadecanoic acid,
22. 2-hydroxytetra-ecosanoic acid,
23. 2-hydroxyeicosanoic acid and
24. mandelic acid,
25. benzoic acid,
26. phenyllactic acid,

27. gluconic acid,
28. galacturonic acid,
29. aleuritic acid,
30. ribonic acid,
31. tartronic acid,
32. tartaric acid,
33. malic acid,
34. fumaric acid,
35. retinoic acid and its derivatives,
36. benzene-1,4-bis(3-methylidene-10-camphorsulphonic acid),
37. **dihydroxyacetone (DHA)**,
38. water-soluble vitamins,
39. starch,
40. bacterial or plant extracts,
41. tocopherol (vitamin E) and its derivatives,
42. **essential fatty acids**,
43. ceramides,
44. **essential oils**
45. plant proteins and their hydrolysates,
46. xanthic derivatives (caffeine, theophylline),
47. beta.-glycyrrhetinic acid,
48. **asiatic acid**,
49. octopirox,
50. retinol and its esters,
51. natural derivatives of the flavonoid family,
52. **vitamin D and its derivatives**,
53. oestradiol,
54. kojic acid,
55. hydroquinone;
56. alpha.-tocopherol or its esters,
57. superoxide dismutases,
58. certain metal-chelating agents;
59. antagonists of substance P and/or of CGRP (calcitonin gene related peptide) such as Iris pallida and strontium salts, and
60. antagonists of substance P and/or of CGRP such as those described in French patent applications FR-A-2,719,474 and FR-A-2,729,855.

The Examiner relied on Simon's disclosure of the above-highlighted cosmetic ingredients (among numerous other cosmetic ingredients) as support for the obviousness rejections. However, the Examiner ignored the fact that nothing in Simon teaches or suggests the specific combinations of DHA, essential fatty acids, essential oils, asiatic acid, and vitamin D and derivative thereof, as positively recited by the pending claims of the present invention.

Simon only discloses selection of one or more active agents from the above-listed sixty (60) compounds or families of compounds, which can lead to **millions of different combinations**. For example, for compositions containing three (3) ingredients out of the sixty (60) ingredients, the total number of possible combinations is C(60,3) = 34,220; and for compositions containing five (5) out of the sixty (60) ingredients, the total number is C(60,5) = 5,461,512 (calculated by the Combination Calculator at *http://fclass.vaniercollege.qc.ca/web/mathematics/real/Calculators/PermsCombs_Calc_1.htm*, visited on September 29, 2006). Simon does not provide any direction or guidance as to which of these millions of combinations is likely to be successful in enhancing the skin's natural lipid barrier. As a matter of fact, Simon does not even contemplate the enhancement of skin lipid barrier. In absence of any direction or guidance from Simon, one ordinarily skilled in the

art would have to try each of these millions of combinations to find out which could achieve the desired result of the present invention, i.e., enhancing the skin lipid barrier.

Therefore, **Simon is insufficient to support a *prima facie* case of obviousness** against the specific combinations recited by the pending claims of the present application.

The secondary references, Bissett, Elias, and Subbiah, disclose uses of individual cosmetic ingredients, such as betunilinic acid, boswellic acid, cholesterol sterol, and sclareolide, among many other cosmetic ingredients. Similar to Simon, such secondary references also fail to teach or suggest the specific combinations of protease inhibitor(s) and cell differentiation enhancer(s), as recited by the pending claims of the present application; nor do they provide any direction or guidance as to which specific combinations from the numerous cosmetic components and ingredients disclosed therein are likely to be successful in enhancing the skin's natural lipid barrier.

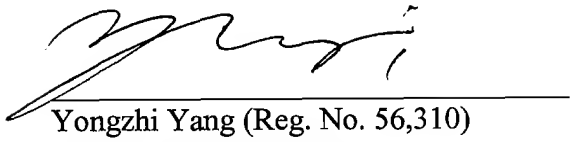
Therefore, **the secondary references do not remedy the deficiency of Simon and thereby also cannot support a *prima facie* case of obviousness against the pending claims of the present application**.

Without any support for a *prima facie* case of obviousness, the Examiner's rejections of the pending claims of the present application under 35 U.S.C. §103 are improper. Correspondingly, Applicants request the Examiner to withdraw such rejections.

In the January 29, 2007 Office Action, the Examiner requested Applicants to provide actual experimental data to demonstrate unexpected results of the present invention. However, as discussed in *In re Piasecki*, 223 USPQ 785 (Fed. Cir. 1984), the Examiner bears the initial burden of establishing a *prima facie* case of obviousness. In the present case, the Examiner has not yet met such initial burden, and Applicants therefore are entitled to grant of the patent without any additional evidence or argument, as indicated by *In re Piasecki*.

Based on the foregoing, all pending claims 4, 6, 8-13, 15-26, 28, 33, and 35 of the present application are patentably distinguished over the art and are in condition for allowance. The Examiner is requested to issue a Notice of Allowance in favor thereof. If any issues require further consideration, the Examiner is requested the contact the undersigned attorney to discuss same.

Respectfully submitted,



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